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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/491,596	01/25/2000	Todd Elliott Piper	1199	8751

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EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/491,596

Applicant(s)

PIPER, TODD ELLIOTT

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1,2,4,6-8,21 and 23-27 is/are allowed.
- 6) ☐ Claim(s) 3,5,9-20,22 and 28-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other

DETAILED ACTION

Request for Continued Examination

1. The transmittal received on 29 May 2002 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/491,596 is acceptable and an RCE has been established. An action on the RCE follows.
2. The objection to claims 1, 21, 37, and 40 is withdrawn in light of the claim amendments.
3. The rejection of claims 4-6 and 23-25 under 35 U.S.C. 112, 2nd paragraph, in the Office action mailed 19 December 2001 under item 3 is withdrawn upon further consideration.
4. The rejection of claims 1-51 under 35 U.S.C. 112, 2nd paragraph, in the Office action mailed 19 December 2001 under item 4 is withdrawn in light of the claim amendments.
5. The rejection of claims 17, 36, and 43 under 35 U.S.C. 112, 2nd paragraph, in the Office action mailed 19 December 2001 under item 5 is withdrawn upon further consideration.
6. The rejection to claim 50 under 35 U.S.C. 112, 2nd paragraph, is withdrawn and replaced with the indefinite rejection below.

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7. The rejection of claims 1-51 under 35 U.S.C. 112, 1st paragraph, in the Office action mailed 19 December 2001 under item 6 is withdrawn in light of the claim amendments.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 14, 17, 33, 36, 41, 43, 45, and 46 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 5,936,148, for the reasons of record stated in the Office action mailed 19 December 2001 under item 3 for claims 1-17 and 21-46. Applicants traverse the rejection in the paper filed 20 May 2002. Applicant's arguments have been fully considered but were not found fully persuasive.

The instantly claimed inbred line and that of 5,936,148 share numerous traits, or differ due to minor morphological variations that would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable

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distinction to PH54H. Further, the designation "PH54H" does not distinguish the instantly claimed seeds and plants from PH1GC, as this appears to be an arbitrarily assigned designation.

Applicants point out that the claims have been amended to include the ATCC deposit number. However, claims 14, 17, 33, 36, 41, 43, 45 and 46 still read on the patented claims. The instantly claimed plants that are derived from crosses and breeding programs are not patentably distinct from the patented plants that are derived from crosses and breeding programs involving PH1GC, as they can express traits that are also expressed by the patented plants.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 3, 5 (amended), 14, 22, 33, 40-46, 50 (amended) and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 3 and 22, the recitation "wherein said plant has been manipulated to be male sterile" renders the claim indefinite. It is not clear if the claim is directed towards detasseled plants, or plants that have been transformed with a gene conferring male sterility. Claims 3, 22, 50, and 51 also appear to broaden the scope of their parent claims. The parent claims are drawn to plants with a defined set of characteristics, and claims 3, 22, 50, and 51 add more characteristics. The following amendments are suggested: 1) in claims 3 and 22, replace "manipulated to be male sterile" with --detasseled--; 2) cancel claims 50 and 51, and add a new claim 52 directed towards a method of producing a male sterile maize plant comprising

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transforming the maize plant of claim 2 with a nucleic acid that confers male sterility, and a new claim 53 directed towards a male-sterile maize plant produced by the method of claim 52.

In claim 5: there is improper antecedent basis for "protoplasts" in line 1. It is suggested that the term be removed from the claim, and that a new claim be introduced directed towards protoplasts produced from the tissue culture of claim 4.

In claim 40: the claim is indefinite because the recitation "comprising" in line 1 does not clearly indicate how many crosses are to be performed by the method. It is suggested that the recitation --F1 hybrid-- be inserted in claim 40, line 4 after "progeny", and in line 5 after "said".

In claims 14, 33, and 46: the recitations "pollen shed", "yield", "grain dry down", "plant height" render the claims indefinite. All corn plants have these traits, and it is not clear how the recitations define the claimed plant. The recitation "Northcentral region of the United States" also renders the claims indefinite, as the states that make up this region are not defined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 9-14, 15-20, and 28-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any F1 hybrid seed produced by crossing PH54H with another, different maize plant; any F1 hybrid plant produced by growing said seed; maize

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plant PH54H transformed with any transgene(s); a method for producing a maize plant that contains one or more transgenes comprising crossing PH54H transformed with any transgene(s) with a non-transformed PH54H plant or a plant of another maize line, and maize plants produced from the method; any descendent of PH54H that expresses at least 2 traits listed in claim 14 that are also expressed by PH54H; any maize plant developed in a breeding program comprising PH54H or part thereof as the starting material; PH54H comprising one or more single gene conversions; an F1 hybrid seed, and plant grown therefrom, produced by crossing a plant having all the morphological and physiological characteristics as PH54H with a different maize line; or plants having all the morphological and physiological characteristics as PH54H and transformed with one or more transgenes, a method comprising crossing said plant with a non-transformed PH54H or plant of another maize line, and plants produced by the method; a maize plant that is any descendent of a maize plant having all the morphological and physiological characteristics as PH54H, and expressing any two of the listed traits that are also expressed by PH54H; any maize plant developed by a breeding program using any maize plant having all the morphological and physiological characteristics as PH54H; a process for producing inbred PH54H comprising planting a collection of hybrids having as one parent PH54H; method for producing PH54H-derived plants, and plants derived by the method.

The specification describes morphological and physiological traits of an inbred corn plant arbitrarily designated "PH54H" (page 15, line 30 to page 16, line 15; Table 1 on pages 17-19; page 35; Tables 2A-2C and Tables 3A-3B on pages 38-42). The specification also indicates that hybrid plants were produced by crossing PH54H to a corn plant designated PH1GD. Numerous

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traits of the PH54H/PH1GD hybrid were compared to other hybrid plants produced by crossing other inbred corn plants (page 36, line 1 to page 37, line 10; Tables 4A-4E, pages 43-47).

However, the specification does not describe the plants produced by the corn breeding programs, transgenic PH54H plants, PH54H plants comprising single gene conversion(s), or by crosses wherein at least one ancestor is corn variety PH54H, other than PH54H/PH1GD. The morphological and physiological traits of the corn plants that are crossed with PH54H, and with progeny of that cross, are unknown, and the description of progeny and descendants of corn plant PH54H are unknown. The description of corn plant PH54H is not indicative of the description of plants and seed produced by the breeding programs and crosses, or of any of its descendants. The claimed invention also encompasses plants that express at least two of the "PH54H traits" listed in claims 14, 33, and 46. However, to say that a plant expresses two traits of another plant is not sufficient information to describe that plant, as numerous corn plants express at least two of the same traits as those expressed by PH54H. Two plant traits do not provide any description of the other traits of a plant. It is possible that the claimed plants inherited the genes governing those traits from an ancestor other than plant PH54H. For example, Carrigan et al. (U. S. Patent No. 5,936,148) describes a corn plant, designated "PH1GC" which has at least two traits in common with PH54H, a relative maturity of 95 based on the Comparative Relative Maturity Rating System for harvest moisture of grain, root lodging resistance, and brittle stalk resistance, for example (col. 10, lines 36-50). The instantly claimed corn plants could have PH1GC as an ancestor, as well as PH54H, in which the relative maturity, root lodging and brittle stalk resistance traits, for example, could have been inherited from PH54H. The claims also encompass plants that do not have to express any of the traits that are expressed by PH54H. The

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specification does not describe any of the traits of such plants, and the morphological and physiological description of PH54H is not indicative of the description of such plants. The description of the PH54H/PH1GD hybrid also does not provide any information concerning the description of any other hybrids. The morphological and physiological traits of PH54H/PH1GD are not indicative of the traits expressed by other hybrids. The descriptions of PH54H and PH54H/PH1GD are also not indicative of any transgenic plant or PH54H plants comprising single gene conversion(s). Transgenes may also be of any gene, including those that effect more than one trait. The morphological and physiological characteristics of any such plant are not described. For example, a transgene that is a transcription factor can effect more than just one gene, and multiple traits. Such plants would express different morphological and physiological traits from 39R62, which are not described. It is suggested that claims 11 and 30 be amended to list the types of transgenes contemplated in the specification, for example disease or pest resistance genes, provided the prior art teaches those isolated genes. Given the breadth of the claims encompassing corn plants expressing at least two traits that are also expressed by PH54H, or any trait, and descendents of PH54H, and lack of guidance of the specification as discussed above, the specification fails to provide an adequate written description of the multitude of corn plants and their parts encompassed by the claims.

11. Claims 18-20 and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The claims are broadly drawn towards maize plant PH54H, or a maize plant having all the morphological and physiological characteristics of PH54H, further comprising one or more single gene conversions.

The specification teaches that single gene conversions, or introgression, of the disclosed maize plant through traditional breeding it contemplated (page 20, lines 16-31). However, the specification does not teach any PH54H plants comprising single gene conversions. It is not clear that single genes may be introgressed into the genetic background of a plant through traditional breeding. Hunsperger et al. (US Patent No. 5,523, 520), Kraft et al. (Theor. Appl. Genet., 2000, Vol. 101, pages 323-326), and Eshed et al. (Genetics, 1996, Vol. 143, pages 1807-1817), for example, teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant.

Hunsperger et al. teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46). Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype specific and loci-dependent in nature (page 323, column 1, lines 7-15). Kraft et al. teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding materials, and therefore it is an unpredictable effect in plant breeding (page 323, column 1, lines 7-15). Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising

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contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). In the absence of further guidance, undue experimentation would be required by one skilled in the art to overcome the difficulties and unpredictability of single gene conversions taught in the prior art.

Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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12. Claims 14, 17, 33, 36, 41, 43, 45, and 46 remain rejected under 35 U.S.C. § 102 (e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 (a) as obvious over Carrigan et al. (U.S. Patent No. 5,936,148). Applicants traverse the rejection in the paper received 29 May 2002. Applicant's arguments have been fully considered but were not found fully persuasive.

The claims broadly encompass a plant, or parts thereof, having characteristics of maize inbred line PH54H, seed or progeny derived from maize plant PH54H, maize plants derived from PH54H, tissue culture derived from PH54H, methods of using said plant in a breeding program; methods to producing PH54H plants comprising one or more transgenes.

Carrigan et al. teach seed of maize inbred line PH1GC, plants produced by growing said seed, and plants and plant parts having all of the physiological and morphological characteristics of inbred line PH1GC. It appears that the claimed plants and seeds of the instant invention may be the same as PH1GC, given that each has a relative maturity of 95 based on the Comparative Relative Maturity Rating System for harvest moisture of grain, resistance to root lodging, and brittle stalk resistance, for example (Table 1; col. 10, lines 29-67). Alternatively, if the claimed plants, plant parts, and seeds of PH54H are not identical to PH1GC, then it appears that PH1GC only differs from the claimed plants, plant parts, and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to PH54H. Carrigan et al. also teach methods for producing hybrid plants wherein a plant of inbred line PH1GC is crossed with itself or another maize plant and crossed multiple times, and maize plant pedigree breeding (col. 2, line 59 to col. 4, line 27; col. 13, line 31 to col. 14, line 34). The process of making the instantly claimed plants does not distinguish the plants

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themselves from those taught by the reference. Thus, the claimed invention was clearly *prima facie* obvious as a whole to one of ordinary skill in the art, if not anticipated by Carrigan et al.

Applicant argue that plants developed utilizing the genetic makeup of PH54H transferred via crosses are within the scope of the invention, and that use of the genetics of PH54H and the plant with part of the genetics of PH54H is within the scope of the invention (response, paragraph bridging pages 8-9). However, the claimed plants may also have derived the traits from other plants in its ancestry, and these plants are also within the scope of the claims.

Applicants argue that if one uses a plant other than PH54H to develop a very similar plant, then this is not within the scope of the invention (response, paragraph bridging pages 8-9). However, the claims do not indicate that the only plant used all of the crosses to derive the claimed plant is PH54H. The claims do not exclude plants that have non-PH54H plants in its ancestry.

Applicant also argues that the plants must have 2 traits from PH54H, that these traits are controlled by many genes, and are evidence that PH54H has provided a genetic contribution to the progeny. However, it is not clear how the presence of the traits in the claimed plant is evidence that the genes controlling them were derived from PH54H, as the non-PH54H plants of the crosses also provided genetic contributions, which may also have included the genes controlling the listed traits.

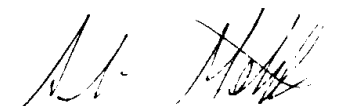
13. Claims 1, 2, 4, 6-8, 21, and 23-27 are allowed. Claims 3, 5, 9-20, 22, 28-51 are rejected.

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Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

August 7, 2002


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER